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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,991	01/10/2007	Graham Francois Duirs	JAMES116.001APC	9007

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EXAMINER	
BUMGARNER, MELBA N	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
09/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/572,991	DUIRS, GRAHAM FRANCOIS	
	Examiner	Art Unit	
	Melba Bumgarner	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/21/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because the abstract should describe the disclosure sufficiently and be within the range of 50 to 150 words. Correction is required. See MPEP § 608.01(b).

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "2" in figure 1.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "the external aperture of the conduit", "a two-way valve system", "the aperture operated by vacuum pulsation" and "the aperture operated by an inductive pulse" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 8, 9, 13, 14, 20, and 24 are objected to because of the following informalities: recitation of "the inner core" in claim 8, "the matrix" in claim 9, "the build up of milk pressures" in claim 13, "the milk pressure" in claim 14, "the body" in claim 20 lack sufficient antecedent basis; grammatical error in claim 24 of "the passage of instruments, applicators, other devices, one or more treatment substances." Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. In claim 26, recitation of "the animal" and in claim 27 recitation of "the external aperture" lack sufficient antecedent basis to the claims.

Claim 31 provides for the use of a device, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 31 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-6, 9-15, 19, 20, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (3,938,517). Anderson discloses a device 20 capable of insertion into a teat orifice 12 wherein the device is capable of being held in position entirely within the teat streak canal 14 and the surface 24 of the device is contoured to be capable of integrating with endogenous keratin to form a composite plug. The device is configured to delivery one or more treatment substances (column 1 line 66) for a period of time. The device is configured to

degrade over time (column 4 line 18). The device is configured to act as a physical barrier (figure 1). The device is made of a preformed matrix impregnated with the substances (column 1 line 53). The treatment substances are contained within the inner core of the device. The treatment substances are delivered by diffusion or dissolution of the matrix (column 4 line 18). The treatment substances are antibacterial substances (column 3 line 40). The device is configured to be capable of withstanding build up of milk pressure or to be dislodged from the streak canal (column 1 lines 60, 63). The device includes surface features to enhance the retention of the device and configured so as to be capable of causing minimal dislodgement of keratin at insertion (figure 2). The device is configured to allow surrounding layer of streak canal to form naturally (column 2 line 41). Anderson discloses a method of treating an animal using the device by inserting the device into a teat orifice during involution, the device capable of being held in the teat canal and the surface of the device contoured to allow formation of an endogenous keratin plug. Anderson shows the healing, delivering treatment substances, and restoration of teat orifice to a natural size which would include material naturally formed in teat canal of keratin (column 2 line 37, column 3 line 34).

10. Claims 1-3, 5, 6, 8, 12, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Zackheim (3,703,898). Zackheim discloses a device 10 capable of insertion into a teat T orifice wherein the device is capable of being held in position entirely within the teat streak canal C and the surface 22 of the device is contoured to integrate with endogenous keratin to form a composite plug. The device is configured to delivery one or more treatment substances (column 1 line 44) for a period of time. The device is configured to act as a physical barrier (figure 5). The device is made of a preformed matrix (column 3 line 6). The treatment

substances 14 are contained within the inner core of the device. The treatment substances are healants (column 1 lines 44, 47). The device is configured to be capable of withstanding build up of milk pressure or to be dislodged from the streak canal. The device includes surface features to enhance the retention of the device and configured so as to cause minimal dislodgement of keratin at insertion (column 2 lines 47). The device is configured to allow surrounding layer of streak canal to form naturally (column 2 line 60). Zackheim discloses a method of treating an animal using the device.

11. Claims 1-3, 5, 6, 9-15, 17, 19, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Sayre (1,957,673). Sayre discloses a device (figure 1) capable of insertion into a teat orifice wherein the device is capable of being held in position entirely within the teat streak canal (page 1, line 6) and the surface of the device is contoured to be capable of integrating with endogenous keratin to form a composite plug. The device is configured to delivery one or more treatment substances (page 1, line 10) for a period of time. The device is configured to act as a physical barrier (page 1, line 26). The device is made of a preformed matrix impregnated with the substances (page 1, line 80). The treatment substances are delivered by diffusion or dissolution of the matrix (page 2 line 46). The treatment substances are antibacterial substances (page 1 line 81). The device is configured to be capable of withstanding build up of milk pressure or to be dislodged from the streak canal (page 2 line 42). The device includes surface features to enhance the retention of the device and configured so as to be capable of causing minimal dislodgement of keratin at insertion (page 2 lines 4, 23). The surface features include a spiral thread (figure 11). Sayre discloses a method of treating an animal using the device.

12. Claims 1-3, 5, 6, 8, 12-19, 21-27, are 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordhamer (3,821,956). Gordhamer discloses a device 10 capable of insertion into a teat orifice (column 1 line 6) wherein the device is capable of being held in position entirely within the teat streak canal (column 1 line 8) and the surface 12 of the device is contoured to be capable of integrating with endogenous keratin to form a composite plug. The device is configured to delivery one or more treatment substances (column 2 line 11) for a period of time. The device is configured to act as a physical barrier. The device is made of a preformed matrix (figure 5). The treatment substances are contained within the inner core of the device (column 3 line 37). The treatment substances are healants (chemotherapeutic drugs, column 2 line 19). The device is configured to be capable of withstanding build up of milk pressure or to be dislodged from the streak canal (column 2 line 16). The device includes surface features to enhance the retention of the device and configured so as to cause minimal dislodgement of keratin at insertion (column 2 line 58). The surface features include grooves 20,21, a spiral thread, plurality of protrusions, a recess 25 which extends substantially the axial length of the device to form a conduit. The recess acts as a reservoir 27 (column 3l line 42). The conduit allows passage of treatment substances, milk (column 2 lines 8,11). The device comprises external aperture of the conduit. The statements of intended use (i.e. operated by vacuum pulsation or an inductive pulse) do not impose any further specific structural limitations in the device and are hence given little patentable weight since the device disclosed in the prior art is capable of being used as claimed. Gordhamer discloses a method of treating an animal using the device.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sayre in view of Reul et al. (4,331,651). Sayre discloses the device having the limitations as described above and the matrix of non-corrosive material such as rubber composition; however, Sayre does not show the matrix of silicone. Real et al. teach a device (body) comprising silicone (column 2 line 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the matrix of Sayre to be of silicone in order to use a physiologically acceptable and release promoting material in view of Reul et al.

15. Claim 28 is rejected as understood, under 35 U.S.C. 103(a) as being unpatentable over Gordhamer in view of Child (4,385,633). Gordhamer discloses the device having the limitations as described above; however, Gordhamer does not show the device having a valve system. Gordhamer teaches a device comprising a valve system 136. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Gordhamer to have a valve system in order to restrict the flow of external material into the conduit. It would have been an obvious matter of choice to one of ordinary skill in the art as to having a two-way valve system instead of one-way valve system, particularly in that Applicant has not provided purpose for two-way valve system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melba Bumgarner whose telephone number is (571)272-4709. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melba Bumgarner/
Primary Examiner, Art Unit 3767